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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,201	02/28/2002	David J. Glass	REG 910A	8028
7590	08/16/2004		EXAMINER	
Laura J. Fischer Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591				GEBREYESUS, KAGNEW H
		ART UNIT	PAPER NUMBER	1652

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	Application No.	Applicant(s)
	10/086,201	GLASS, DAVID J.
	Examiner	Art Unit
	Kagnew H Gebreyesus	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 27 July 2004.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 10-14 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 10-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of 23 April, 2004 in the reply filed on 5 April, 2004 is acknowledged. The traversal is on the ground(s) that it would not present an additional search burden for the co-examination of both Group IV and Group II simultaneously. This is not found persuasive because while the search necessary for examination of the two groups overlaps, it is not coextensive, examination of Group II would require search of subclasses unnecessary for the search of Group IV, for example 435/325.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-9 and 15-41 have been withdrawn from further consideration by examiner, pursuant to 37 CFR 1.142 (b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Claim Objections***

All claims containing the abbreviations "SHIP2" and "AKT" are objected to because abbreviations should be expanded the first time they are used in the claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 3, 4, 10, 19 and 20 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Does "SHIP2" mean a single human protein or groups of proteins with a particular function or other identifying characteristics?

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 10-14 rejected under 35 U.S.C. 103(a) as being obvious over Rommel et. al. 1999 in view of any one of Habib et.al. 1998, or Ishihara et. al., 1999 or Taylor et. al. 2000.

Rommel et. al. teach the role of two pathways in the process of skeletal muscle hypertrophy. They describe that an AKT/PI3-kinase pathway promotes hypertrophy and that the Raf-MEK-ERK pathway results in smaller, thinner myotubes in C2C12 cells.

Furthermore the authors describe the finding that when constitutively active AKT is transfected in C2C12 cells it promotes muscle hypertrophy (Rommel, see page 1738 fig.

1(c) and (g)) and that this would be clinically important for treating muscle atrophy (page 1741). In the instant case the inventor describes an AKT construct transfected in C2C12 cells and by inhibiting SHIP2 activation of AKT occurs leading to inhibition of atrophy or hypertrophy occurs. Habib et.al. 1998, and Ishihara et. al., 1999 as well as Taylor et. al. 2000 all teach that SHIP2 inhibits AKT activation therefore screening for inhibitors of SHIP2 activity would be suggested and specifically an assay which directly measures increased AKT activation (since this is the effect desired) would be obvious to a person of ordinary skill in the art.

Taken together, the above reference of methodology of screening and the references showing the correlation between SHIP2 and AKT activity, it would clearly be obvious to the ordinary artisan in the art to make and use the claimed screening method disclosed in the present application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus  
Art Unit 1652

*Rebecca Prouty*  
REBECCA E. PROUTY  
PRIMARY EXAMINER  
CPE/PTO  
1600